

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Anti-Infective Drugs Advisory Committee (AIDAC) Meeting

FDA White Oak Campus, 10903 New Hampshire Avenue
Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, Maryland
January 22, 2015

AGENDA

The committee will discuss new drug applications (NDAs) 207-500 and 207-501, isavuconazonium sulfate capsules and isavuconazonium sulfate for injection, sponsored by Astellas Pharma Global Development, Inc., respectively for the proposed indications of treatment of invasive aspergillosis and mucormycosis.

8:00 a.m.	Call to Order and Introduction of Committee	Thomas A. Moore, MD, FACP, FIDSA Acting Chairperson, AIDAC
8:10 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh. Designated Federal Officer, AIDAC
8:15 a.m.	FDA Introductory Remarks	John Alexander, MD, MPH Clinical Team Leader Division of Anti-Infective Products (DAIP) Office of Antimicrobial Products (OAP) Office of New Drugs (OND), CDER, FDA
8:30 a.m.	APPLICANT PRESENTATIONS	Astellas Pharma Global Development, Inc.
	Compound Overview and Clinical Pharmacology	Bernhardt Zeiher, MD, FACP, FCCP Executive Vice President, Global Development and Therapeutic Area Head Immunology and Infectious Diseases Astellas Pharma Global Development, Inc.
	Disease Background and Unmet Need	Andrew Ullmann, MD Professor of Infectious Diseases University of Wurzburg, Germany
	Efficacy	Rochelle Maher, MS Senior Director, Global Development Project Leader, Infectious Diseases Astellas Pharma Global Development, Inc.
	Safety	Salim Mujais, MD Vice President, Medical Head Infectious Disease/Immunology/Transplant Astellas Pharma Global Development, Inc.

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Benefit-Risk

Bernhardt Zeiher, MD, FACP, FCCP

9:45 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:25 a.m. **FDA PRESENTATIONS**

Clinical Efficacy of Isavuconazonium
for the Treatment of Invasive
Aspergillosis

Cheryl Dixon, PhD
Statistical Reviewer
Division of Biometrics IV (DB IV)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

Clinical Efficacy of Isavuconazonium
for the Treatment of Invasive
Mucormycosis and Overview of Safety

Edward Weinstein, MD, PhD
Medical Officer
DAIP, OAP, OND, CDER, FDA

11:25 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**